

Message

From: Sinks, Tom [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=001007B7D256453A8A19B91DF704E22C-SINKS, TOM]
Sent: 4/5/2018 6:34:39 PM
To: McGartland, Al [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5fe25fc1df634f9798675527e0070429-AMcGartl]
Subject: FW: new NIH position on certificates of confidentiality is also relevant to the HONEST ACT
Attachments: Barnes Cert of Confidentiality 21-Century-Cures-Act Bloomberg Law 10-4-2017.pdf

Al – here is the language from the 21st Century Cures Act and a journal article related to it. Also here is the website for NIH re this ...

<https://humansubjects.nih.gov/coc/index>

From: Sinks, Tom
Sent: Tuesday, March 20, 2018 4:19 PM
To: Sinks, Tom <Sinks.Tom@epa.gov>
Cc: Teichman, Kevin <Teichman.Kevin@epa.gov>
Subject: RE: new NIH position on certificates of confidentiality is also relevant to the HONEST ACT

Language passed in the 21st Century Cures Act states the following ... <https://www.gpo.gov/fdsys/pkg/PLAW-114publ255/pdf/PLAW-114publ255.pdf>

SEC. 1012. PRIVACY PROTECTION FOR HUMAN RESEARCH SUBJECTS.

(a) IN GENERAL.—Subsection (d) of section 301 of the Public Health Service Act (42 U.S.C. 241) is amended to read as follows:

“(d)(1)(A) If a person is engaged in biomedical, behavioral, clinical, or other research, in which identifiable, sensitive information is collected (including research on mental health and research on the use and effect of alcohol and other psychoactive drugs), the Secretary, in coordination with other agencies, as applicable—

“(i) shall issue to such person a certificate of confidentiality to protect the privacy of individuals who are the subjects of such research if the research is funded wholly or in part by the Federal Government; and

“(ii) may, upon application by a person engaged in research, issue to such person a certificate of confidentiality to protect the privacy of such individuals if the research is not so funded.

“(B) Except as provided in subparagraph (C), any person to whom a certificate is issued under subparagraph (A) to protect the privacy of individuals described in such subparagraph shall not disclose or provide to any other person not connected with the research the name of such an individual or any information, document, or biospecimen that contains identifiable, sensitive information about such an individual and that was created or compiled for purposes of the research.

“(C) The disclosure prohibition in subparagraph (B) shall not apply to disclosure or use that is—

“(i) required by Federal, State, or local laws, excluding instances described in subparagraph (D);

“(ii) necessary for the medical treatment of the individual to whom the information, document, or biospecimen pertains and made with the consent of such individual;

“(iii) made with the consent of the individual to whom the information, document, or biospecimen pertains; or

“(iv) made for the purposes of other scientific research that is in compliance with applicable Federal regulations governing the protection of human subjects in research.

“(D) Any person to whom a certificate is issued under subparagraph (A) to protect the privacy of an individual described in such subparagraph shall not, in any Federal, State, or local civil, criminal, administrative, legislative, or other proceeding, disclose or provide the name of such individual or any such information, document, or biospecimen that contains identifiable, sensitive information about the individual and that was created or compiled for purposes of the research, except in the circumstance described in subparagraph (C)(iii).

“(E) Identifiable, sensitive information protected under subparagraph (A), and all copies thereof, shall be immune from the legal process, and shall not, without the consent of the individual to whom the information pertains, be admissible as evidence or used

130 STAT. 1050 PUBLIC LAW 114–255—DEC. 13, 2016
for any purpose in any action, suit, or other judicial, legislative, or administrative proceeding.

“(F) Identifiable, sensitive information collected by a person to whom a certificate has been issued under subparagraph (A), and all copies thereof, shall be subject to the protections afforded by this section for perpetuity.

“(G) The Secretary shall take steps to minimize the burden to researchers, streamline the process, and reduce the time it takes to comply with the requirements of this subsection.

“(2) The Secretary shall coordinate with the heads of other applicable Federal agencies to ensure that such departments have policies in place with respect to the issuance of a certificate of confidentiality pursuant to paragraph (1) and other requirements of this subsection.

“(3) Nothing in this subsection shall be construed to limit the access of an individual who is a subject of research to information about himself or herself collected during such individual’s participation in the research.

“(4) For purposes of this subsection, the term ‘identifiable, sensitive information’ means information that is about an individual and that is gathered or used during the course of research described in paragraph (1)(A) and—

“(A) through which an individual is identified; or

“(B) for which there is at least a very small risk, as determined by current scientific practices or statistical methods, that some combination of the information, a request for the information, and other available data sources could be used to deduce the identity of an individual.”.

(b) APPLICABILITY.—Beginning 180 days after the date of enactment of this Act, all persons engaged in research and authorized by the Secretary of Health and Human Services to protect information under section 301(d) of the Public Health Service Act (42 U.S.C. 241(d)) prior to the date of enactment of this Act shall be subject to the requirements of such section (as amended by this Act).

SEC. 2013. PROTECTION OF IDENTIFIABLE AND SENSITIVE INFORMATION.

Section 301 of the Public Health Service Act (42 U.S.C. 241) is amended by adding at the end the following:

“(f)(1) The Secretary may exempt from disclosure under section 552(b)(3) of title 5, United States Code, biomedical information that is about an individual and that is gathered or used during the course of biomedical research if—

“(A) an individual is identified; or

“(B) there is at least a very small risk, as determined by current scientific practices or statistical methods, that some combination of the information, the request, and other available data sources could be used to deduce the identity of an individual.

“(2)(A) Each determination of the Secretary under paragraph

(1) to exempt information from disclosure shall be made in writing and accompanied by a statement of the basis for the determination.

“(B) Each such determination and statement of basis shall be available to the public, upon request, through the Office of the Chief FOIA Officer of the Department of Health and Human Services.

42 USC 241 note.

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“(3) Nothing in this subsection shall be construed to limit a research participant’s access to information about such participant collected during the participant’s participation in the research.”.

SEC. 2014. DATA SHARING.

(a) IN GENERAL.—Section 402(b) of the Public Health Service Act (42 U.S.C. 282(b)) is amended—

(1) in paragraph (23), by striking “and” at the end;

(2) in paragraph (24), by striking the period and inserting “; and”; and

(3) by inserting after paragraph (24) the following:

“(25) may require recipients of National Institutes of Health awards to share scientific data, to the extent feasible, generated from such National Institutes of Health awards in a manner that is consistent with all applicable Federal laws and regulations, including such laws and regulations for the protection of—

“(A) human research participants, including with respect to privacy, security, informed consent, and protected health information; and

“(B) proprietary interests, confidential commercial information, and the intellectual property rights of the funding recipient.”.

(b) CONFIDENTIALITY.—Nothing in the amendments made by subsection (a) authorizes the Secretary of Health and Human Services to disclose any information that is a trade secret, or other privileged or confidential information, described in section 552(b)(4) of title 5, United States Code, or section 1905 of title 18, United States Code, or be construed to require recipients of grants or cooperative agreements through the National Institutes of Health to share such information.

From: Sinks, Tom

Sent: Monday, March 19, 2018 2:26 PM

To: Shoaff, John <Shoaff.John@epa.gov>

Subject: new NIH position on certificates of confidentiality is also relevant to the HONEST ACT

Certificates of Confidentiality for NIH Funded Research

NIH awardees no longer have to apply for a CoC.

Per Section 2012 of the 21st Century Cures Act as implemented in the 2017 NIH Certificates of Confidentiality Policy, all ongoing or new research funded by NIH as of December 13, 2016 that is collecting or using identifiable, sensitive information is automatically issued a CoC. Compliance requirements are outlined in the NIH Grants Policy Statement, which is a term and condition of all NIH awards.

This policy applies to NIH funded:

- Grants
- Cooperative Agreements
- R&D Contracts
- Other Transaction Awards
- NIH's own intramural research

How do I know if my NIH funded research project is covered by a CoC?

Research in which identifiable, sensitive information is collected or used, including research that

- Meets the definition of human subjects research, including exempt research in which subjects can be identified
- Is collecting or using human biospecimens that are identifiable or that have a risk of being identifiable
- Involves the generation of individual level human genomic data
- Involves any other information that might identify a person

If your research meets any of the above criteria then your research data or information is automatically protected by a CoC from NIH.

What does having a CoC mean I need to do?

1. **Researchers with a CoC may ONLY disclose identifiable, sensitive information in the following circumstances:**
 - if required by other Federal, State, or local laws, such as for reporting of communicable diseases
 - if the subject consents; or
 - for the purposes of scientific research that is compliant with human subjects regulations
2. **AND you must ensure that anyone who is conducting research as a subawardee or receives a copy of identifiable sensitive information protected by the policy understand they are they are also subject to the disclosure restrictions, even if they are not funded directly by NIH.**

How do I document that I have a CoC for my NIH funded Research?

NIH will no longer issue a physical certificate. You may point to your Notice of Award and the NIH Grants Policy Statement as documentation of the CoC protection.

Will I ever need to extend or amend my CoC?

If your NIH-funding will or has ended but the collection of new data from research participants will continue without NIH-funding you will need to apply for a CoC for continuity of protections using the CoC application system. If your NIH funding will or has ended but your study has completed all enrollment and data collection, there is no need to extend the Certificate. Sensitive, identifiable research information maintained by investigators during any time a Certificate is in effect, is protected permanently.

Where can I learn more?

Read the [2017 NIH Certificates of Confidentiality Policy](#).

Have a CoC Question?

Please address your inquiries to: NIH Office of Extramural Research: NIH-CoC-Coordinator@mail.nih.gov

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